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A Restatement of Health Care Law

David Orentlicher†

INTRODUCTION

While the value of a health care law Restatement may once have been uncertain, that is no longer the case. With advances in research and technology, health care has become an increasingly important factor in the economy and legal system of the United States. National spending has risen to more than 2.7 trillion dollars a year (about 18% of GDP), and health care law now encompasses a broad range of key doctrines, from medical malpractice and end-of-life decision making to health care financing and food and drug regulation. As health care and the laws that govern it have increased in importance, the value of a Restatement of Health Care Law has grown as well. There would be much to be gained from a health care law restatement. It could:

- Serve the traditional Restatement roles of describing the landscape for central doctrines in the field and shaping doctrinal reform (e.g., treatment withdrawal from incompetent persons or the scope of physician disclosures for informed consent) (Part I of this article),
- Untangle complicated doctrines and indicate how the law could be streamlined (e.g., ERISA) (Part II), and
- Indicate when health care exceptionalism makes sense (e.g., public health regulations or health care antitrust law) (Part III).

A health care law Restatement would enhance its contributions substantially by considering not only legal principle and doctrine but also empirical evidence. Many legal issues in

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health care can be better understood by considering how health care decisions are actually made, whether by patients, physicians, hospitals, or other participants in the health care system. By incorporating the lessons of empirical studies, authors of a health care law Restatement would place their analyses on much firmer ground.

I. DESCRIBING THE LEGAL LANDSCAPE

For a number of important doctrines in health care law, states have developed legal rules that overlap to some extent but also diverge on key principles. A Restatement could provide courts, legislators, practitioners, and scholars with a very helpful understanding of the legal landscape for these doctrines. The right to have life-sustaining treatment withdrawn and the scope of disclosure for informed consent are good examples. In addition, by exploring the justifications for the different legal rules and examining the light that empirical evidence sheds, a Restatement could indicate how the law should develop in the future.2

A. Withdrawal of Life-Sustaining Treatment

Since the Karen Quinlan case in 1976,3 the right to refuse life-sustaining treatment has become firmly established, as state and federal courts have answered a number of questions in a common way. For example, the right to refuse does not vary with the patient's medical condition—whether young and relatively healthy or old and terminally ill, all individuals may decline unwanted health care, even if death may result. Similarly, the right does not depend on whether the treatment is complex and very invasive, such as artificial ventilation or surgery, or simple and not very intrusive, such as antibiotics or a blood transfusion. Undoubtedly, patients' decisions will be influenced by their prognoses and the kinds of treatment at stake, but those are factors for individuals to weigh for themselves.4

The consensus on the right to refuse treatment begins to unravel when the right is invoked on behalf of patients who have

2 Indeed, Restatements have long done more than simply restate the law. At times, they influence reforms of the law by siding with positions that have been taken by a minority, rather than majority, of courts. Herbert Wechsler, The Course of the Restatements, 55 A.B.A. J. 147, 149-50 (1969); Charles W. Wolfram, The Concept of a Restatement of the Law Governing Lawyers, 1 GEO. J. LEGAL ETHICS 195, 196-97 (1987).


4 MARK A. HALL, MARY ANNE BOBINSKI & DAVID ORENTLICHER, HEALTH CARE LAW AND ETHICS 527, 536-40 (8th ed. 2013) [hereinafter HEALTH CARE LAW].
lost decision-making capacity. A person suffering from dementia or other cognitive impairments retains the right, but states vary when it comes to the rules that they employ for deciding when life-sustaining treatment may be withheld or withdrawn from a mentally incapacitated patient.\(^5\)

In particular, states diverge when patients can no longer speak for themselves and they have not left clear evidence of their wishes. When patients have written a living will, appointed a surrogate decision maker, or clearly expressed their preferences in other ways, those preferences govern. The law looks for guidance from the patients themselves. But in the absence of "clear and convincing evidence,"\(^6\) different states take different approaches.

In some states, courts or legislatures have concluded that treatment decisions should be guided as much as possible by the patient's preferences and values. In these states, family members or other surrogate decision makers may draw on their understanding of what the patient likely would desire to make a "substituted" judgment for the patient and decide whether to authorize treatment.\(^7\)

In other states, decisions are to be made on the basis of the patient's best interests. In these states, treatment decisions are guided by the surrogate's objective balancing of the benefits and harms of treatment.\(^8\)

Several states have taken a more nuanced approach, with different standards depending on the patient's medical condition. The better the prognosis, the more difficult it is to withhold or withdraw life-sustaining treatment. On one hand, if patients are terminally ill or permanently unconscious, then surrogates are able to authorize or refuse life-sustaining treatment based on their sense of the patient's preferences. But if the patient is neither terminally ill nor permanently unconscious (e.g., has Alzheimer's disease and is expected to live for a few more years), then treatment generally must be provided. This nuanced approach reflects an important trend, with adoption in several states, either by courts, as in California, &

\(^5\) *Id.* at 570.

\(^6\) Courts across the states will rely on the patient's previously expressed wishes when there is clear and convincing evidence of the patient's wishes. *Id.* at 570.

\(^7\) *Id.* at 572. Questions can arise when family members disagree, and court battles can ensue. See, e.g., *In re Schiavo*, 780 So. 2d 176 (Fla. Dist. Ct. App. 2001) (disagreement between patient's husband and her parents).

\(^8\) *HEALTH CARE LAW, supra* note 4, at 570.
Michigan, New Jersey, Pennsylvania, and Wisconsin, or by legislatures, as in Illinois, Maryland, and New York.\textsuperscript{9}

Some states add an additional nuance. There tends to be little resistance when family members or other surrogates refuse major surgery, artificial ventilation, or other aggressive treatment for seriously ill patients. But legislators and courts are more likely to object when surrogates want to withhold artificial nutrition and hydration.\textsuperscript{10}

There would be considerable benefit alone from a thorough and authoritative description of the rules for withdrawing life-sustaining treatment. Scholars vary in their characterization of existing doctrine,\textsuperscript{11} and a Restatement would be valuable to courts and legislatures trying to reconcile the differences in viewpoint.

Might there be even greater benefit if a Restatement encouraged the development of legal rules in one direction or another? Restatements often have served as important advocates for legal reform, and there is much at stake with decisions about treatment at the end of life.

On the basis of principle, there are good arguments for all of the different approaches to decision making for incompetent patients who have not left clear expressions of their wishes. For example, relying on an assessment of the patient's likely preferences is most consistent with the principles of self-determination that undergird the right to refuse treatment. A best interest standard, on the other hand, recognizes that people's interests change over time and that people's preferences when they are healthier or younger may not serve their interests well when they become much sicker or older. Rather than have surrogates act on the basis of what they think patients would want, it is argued, the law should instruct surrogates to weigh the benefits and burdens of proposed care and agree to treatment as long as patients can get some

\textsuperscript{9} Id. at 572-75.

\textsuperscript{10} Id. at 582, 585; see also Cruzan v. Harmon, 760 S.W.2d 408, 423-24 (Mo. 1988). In most of the nutrition and hydration cases, the courts do not limit their holdings to withdrawal of nutrition or hydration, but indicate that their standards apply to any life-sustaining treatment. See, e.g., Conservatorship of Wendland, 28 P.3d 151, 175 (Cal. 2001); In re Martin, 538 N.W.2d 399, 413 (Mich. 1995). Nevertheless, court challenges are less likely to arise for treatments more aggressive than artificial nutrition and hydration, such as major heart surgery.

\textsuperscript{11} Compare HEALTH CARE LAW, supra note 4, at 573-74 (observing that the nuanced approach, with its different standards based on the patient's medical condition, has become the predominant one), with ALAN MEISEL & KATHY L. CERMINARA, THE RIGHT TO DIE: THE LAW OF END-OF-LIFE DECISIONMAKING 4-15 (3d ed. Supp. 2009) (describing substituted judgment as the predominant approach).
enjoyment from life (e.g., from their interactions with others) and are not suffering from pain or other discomfort from their illnesses or treatments.  

But if principle is indeterminate, consideration of empirical evidence can point us in one direction or another. For example, we know that patients when healthy underestimate the quality of life that they will experience if they become disabled. Previously expressed wishes may not be as good a guide as we think for medical treatment decisions. And people tend to recognize that. A number of studies have found that most patients do not want their family members and physicians to follow their wishes strictly. Patients typically want their surrogate decision makers to have some or even a great deal of leeway to make their own judgments about what is best for the patients. In other words, empirical evidence suggests that a best interests standard makes more sense than a substituted judgment standard for patients who have not left clear and convincing evidence of their wishes (and even so for patients who have left clear evidence of their wishes).

In sum, a thoughtful synthesis of legal principle and empirical evidence can provide considerable benefit to those trying to understand or improve the rules that govern end-of-life decision making.

A Restatement for health care law also could clarify and guide legal doctrine for informed consent.

B. Informed Consent and Physician-Specific Characteristics

When physicians recommend coronary artery bypass surgery or other procedures, they must obtain their patients' informed consent before proceeding. Principles of informed consent require physicians to disclose the expected benefits, potential risks, and other material information about the

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13 HEALTH CARE LAW, supra note 4, at 576.

14 Id. at 576-77 (citing Christina M. Puchalski et al., Patients Who Want Their Family and Physician to Make Resuscitation Decisions for Them: Observations from SUPPORT and HELP, 48(5) J. AM. GERIATRICS SOC. S84 (2000); Ashwini Sehgal et al., How Strictly Do Dialysis Patients Want Their Advance Directives Followed?, 267 JAMA 59 (1992); Daniel P. Sulmasy et al., How Would Terminally Ill Patients Have Others Make Decisions for Them in the Event of Decisional Incapacity, 55 J. AM. GERIATRICS SOC. 1981 (2007). Thus, even when patients have left clear expressions of their wishes, it is not clear that those wishes should govern.
proposed procedure. On this, there is a consensus in medical ethics and the law. But do the requirements of informed consent include disclosure by physicians of information about themselves? For example, must physicians tell patients how many times they have performed a particular surgery and what their success rates are? What about any history of alcohol abuse or the presence of conflicts of interest? There are a number of court decisions on this question, but doctrine remains unsettled.

Considerations of principle suggest that physicians ought to disclose relevant information about themselves. The presence of a conflict of interest might influence the physician's judgment and give a patient reason to discount the physician's advice. Or a physician's greater experience performing a particular procedure may make it more likely that surgery will have the desired effect.

Yet, courts come down on both sides. Some require disclosure, while others do not. Still other courts require disclosure only when patients ask. For courts that do not require disclosure, patients learn about average benefits and risks of a proposed treatment but not about the potential benefits and risks that they actually face. These patients simply are not fully informed before they give consent.

If a Restatement in health care law came down on the side of disclosure, it could push informed consent doctrine in that direction. Doctrine would line up better with principle.

But that may not be the best result. It turns out that faithful adherence to principles of informed consent may lead at times to counterproductive results. For example, consider the potential impact when physicians disclose to patients that they have a financial conflict of interest. Studies that look at

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16 HEALTH CARE LAW, supra note 4, at 239-43.

17 See, e.g., Howard v. Univ. of Med. & Dentistry, 800 A.2d 73, 85 (N.J. 2002) (recognizing cause of action when patient alleged that physician misrepresented his credentials and experience after being asked about them).

18 Financial conflicts of interest for physicians refer to situations in which a doctor's professional judgment might be influenced by the potential for personal economic gain. Aaron S. Kesselheim & David Orentlicher, Insights from a National Conference: "Conflicts of Interest in the Practice of Medicine," 40 J.L. MED. & ETHICS 436, 436-37 (2012). For example, if a physician owns an MRI machine, the physician may be more likely to recommend MRI scans than if the physician referred patients to
the effect of such disclosures find that disclosure may make physicians less concerned about their conflicts and patients more likely to agree to treatment. Once having disclosed their conflicts, physicians may feel that they have satisfied their moral obligations and therefore may feel freer to take action that the financial incentive encourages. For patients, the disclosure may make it difficult to take the conflict into account. Patients may worry that a refusal of the physician’s recommendation will be seen as a sign that the patient does not trust the physician, that the patient believes the conflict clouds the physician’s judgment. Patients may not want to offend the physician and therefore may agree to treatment from the physician when they really would prefer to decline.19

Perhaps the answer to the problem of counterproductive disclosures would be to rely less on physician disclosure and more on other ways to protect patients. For example, if physician disclosures may embolden physicians and inhibit patients, we could turn to other ways for patients to become informed. Indeed, steps already are being taken to do just that. Governmental and independent bodies publish “report cards” based on measures of the quality of care provided, which can inform patients about their doctors.20 In addition, under the Affordable Care Act (ACA), the federal government will publish data online about payments from pharmaceutical, medical device, and biotechnology companies to doctors.21

Besides making it possible for patients to learn about their physicians from sources other than the physicians themselves, concerns about physicians’ personal characteristics can be addressed in other ways. Insurers can play an important role. If a patient needs a complicated surgical procedure, the patient’s insurer can identify a list of well-qualified physicians independent facilities for their MRI scans. Christopher Robertson, Susannah Rose & Aaron S. Kesselheim, Effect of Financial Relationships on the Behaviors of Health Care Professionals: A Review of the Evidence, 40 J.L. MED. & ETHICS 452, 453-54 (2012).


20 Twerski & Cohen, supra note 15, at 3-5.

from which the patient could choose. Or patients could be protected from serious conflicts of interest by prohibitions against the conflicts. Under ethical guidelines and federal law, for example, physicians may not engage in a number of “self-referral” practices, such as referring patients for MRI scans to facilities in which the physicians hold investment interests.

As courts, legislators, and other policy makers consider their options for dealing with the risks that physicians may pose to their patients from inexperience, conflicts of interest, or other factors, a health care law Restatement could provide much needed guidance. And that guidance would be on stronger ground if it reflected both principle and empirical evidence.

II. UNTANGLING COMPLICATED DOCTRINES

Legal rules are never as precise as we might like, and health care law has its share of fuzzy doctrine. A Restatement could help courts, legislators, practitioners, and scholars by untangling existing judicial opinions to the extent that untangling is possible. In addition, to the extent that there are unresolved questions, a Restatement could suggest how doctrine should be developed in a way that best serves the interests of patients and providers of health care services. The Employee Retirement Income Security Act of 1974 (ERISA) provides a useful example.

A. ERISA

For decades, courts and health care law scholars have struggled with the application of ERISA to health care
regulation. Although the passage of ERISA was driven by concerns about abuses in private pension plans, the act also covers other employee fringe benefits, including health care benefits. ERISA created a uniform regime of federal regulation to supplant the patchwork of state regulation for employee benefit plans. However, many problems of interpretation have arisen for ERISA and health care benefits because the statute does not purport to regulate insurance. On one hand, ERISA is supposed to preempt any state law that "relates to" an employee benefit plan and substitute ERISA’s framework of federal regulation. But on the other hand, the statute’s preemption of state law does not extend to state insurance law—ERISA leaves insurance regulation to the states.

The exclusion of insurance leads to an important question. When states regulate the health care coverage that individuals receive from their employers, are the states regulating a fringe benefit of employment (not permitted under ERISA), or are they regulating insurance (permitted under ERISA)? And it gets even more complicated. A state may argue that ERISA preemption is not triggered at all for a state law since the state is regulating doctors or hospitals rather than health care coverage. Or an employer may be able to escape the state regulation of health care insurance that is permitted under ERISA by self-insuring.

Given all of the complexities of ERISA and health care, a Restatement would be very helpful simply by sorting through the different judicial interpretations and indicating how they play out. In addition, to the extent that current interpretations leave uncertainty about the application of ERISA, a Restatement could recommend an optimal application.

This article will consider how a Restatement could address the problem of small employers, self-insurance, and ERISA.

28 HEALTH CARE LAW, supra note 4, at 1060.
29 Jost & Hall, supra note 27 (manuscript at 10-11).
B. Self-Insured Small Employers

As mentioned, ERISA allows employers to escape state regulation of health care insurance by self-insuring.\(^{33}\) At the time of ERISA's enactment, only four percent of employees received their coverage through self-insured plans.\(^{34}\) Since the enactment of ERISA, self-insurance has become much more common for employers, with 60% of employees in self-insured plans in 2012.\(^{35}\)

Traditionally, self-insurance has been much more prevalent among large employers. According to one study, less than one in six workers in firms with fewer than 101 employees were enrolled in self-insured plans, while more than three in five workers in firms with more than 500 employees were enrolled in self-insured plans.\(^{36}\) A more recent study pegged self-insurance at 93% for workers at firms with at least 5,000 employees but only 15% for workers at firms with 3-199 employees.\(^{37}\)

With the passage of the Affordable Care Act, self-insurance has become much more attractive for many small employers. ACA imposes standard “community ratings” for health care insurance, which reflect the costs of all persons, including relatively sick people.\(^{38}\) Self-insured employers bear the costs of their employees only. Thus, for small employers with a relatively healthy workforce, health care costs will be lower from self-insurance than from purchasing an insurance policy, and these employers will have a strong incentive to take

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\(^{33}\) There are other benefits to self-insuring as well, including greater control over plan design and administration and lower administrative costs. Troy Paredes, Note, Stop-Loss Insurance, State Regulation, and ERISA: Defining the Scope of Federal Preemption, 34 HARV. J. ON LEGIS. 233, 249 (1997).


\(^{37}\) Kaiser Family Foundation, supra note 35, at Exhibit 10.3; see also Matthew Buettgens & Linda J. Blumberg, Small Firm Self-Insurance Under the Affordable Care Act, COMMONWEALTH FUND ISSUE BRIEF 4 (Nov. 2012) (observing that “[c]urrent stop-loss plans generally require firms to accept a significant amount of risk, so self-insurance is much less common among small firms than among large ones”).

\(^{38}\) In other words, ACA solves the problems that currently exist for sick individuals or employer groups with relatively unhealthy workers who face unaffordable premiums for health care insurance. Instead of charging people or groups based on their own expected costs of care, insurers will calculate standard, community rates for all customers. Nat’l Fed’n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2585 (2012). There will be some variation in premiums, based on age, costs of care in the geographic region, and whether people smoke or not. 42 U.S.C. § 300gg(a) (2011).
the self-insurance route.\textsuperscript{39} Moreover, these employers need not worry about the possibility that some of their employees will become unexpectedly sick and that their health care costs will become unaffordable. If a small employer’s workforce becomes relatively unhealthy, the employer can abandon self-insurance and purchase a community-rated plan at an ACA health care insurance exchange. In other words, employers can self-insure when it is cheaper to do so and purchase insurance when that alternative is cheaper.

The self-insurance option poses two significant problems for health care policy. First, it may compromise ACA’s goal of making insurance more affordable for small employers. Before ACA, there were many obstacles to affordable health care coverage for small employers. Small groups have less negotiating leverage, they face higher administrative costs, and because their costs are less predictable, insurers charge more to cover the greater actuarial uncertainty.\textsuperscript{40} For businesses whose employees have significant medical needs, the costs of health care coverage are even higher. ACA addresses these obstacles by creating a single, large risk pool for small employers and requiring insurers to charge the standard community rate to all small employers.\textsuperscript{41} But if small employers can stay out of the risk pool when they have healthy employees and enter the risk pool when they have unhealthy employees, they can engage in the kind of adverse selection that destabilizes health care insurance markets—if only unhealthy workforces purchase insurance, health care premiums rise and become less affordable, causing the least unhealthy workforces to drop out of the market and driving prices higher again.\textsuperscript{42}

Self-insured employers can undermine ACA in a second way. By self-insuring, small employers can avoid many of the consumer-protection regulations passed by ACA. For example, self-insured plans are not bound by ACA’s requirement that at least 80 or 85% of premium revenues be spent on medical

\textsuperscript{39} Insurance costs will be lower also because self-insured employers will not have to pay the annual premium surcharge that ACA imposes on health insurers and because self-insured employers will not have to meet the essential health benefit requirements of ACA. Employees in a relatively healthy workforce may be satisfied with a more parsimonious plan. Buettgens & Blumberg, supra note 37, at 4-5.

\textsuperscript{40} Jost & Hall, supra note 32, at 2.

\textsuperscript{41} Id. at 2-5. ACA also addresses the problem of health care insurance being unaffordable for small employers with low-wage employees by expanding Medicaid eligibility, providing subsidies for low-income workers who make too much to qualify for Medicaid, and providing tax credits for small employers that provide health care coverage.

\textsuperscript{42} Id. at 10; Buettgens & Blumberg, supra note 37, at 5.
benefits as opposed to administrative costs or profits (the "medical loss ratio" requirement).43

Some states have tried to prevent small firms from exploiting the self-insurance option by regulating the "stop-loss" policies that play an integral role in self-insurance. Small employers cannot afford to truly self-insure—they could be financially devastated if just a few employees incur very high medical costs. Hence, self-insured employers purchase stop-loss policies that transfer their liability for any very high costs that their employees might incur.44 States have limited the use of stop-loss policies by setting minimum "attachment" points at which a stop-loss policy can kick in. For example, the regulation might require employers to cover the first $30,000 for each employee. With minimum attachment points, employers are able to take advantage of the self-insurance option only if they are truly engaged in self-insurance.

In other words, imposing attachment points does not represent unfairness to small employers. The regulation of stop-loss policies simply prevents small employers from purporting to self-insure but shifting most of the risk to an insurance company and therefore not really self-insuring.

C. ERISA and a Restatement

While regulations of stop-loss policies can preserve the viability of the small group health insurance market, and a number of states have enacted such regulations, some court decisions have cast a cloud on their acceptability under ERISA. A Restatement of Health Care Law could be important in lifting that cloud.

In a leading case, the U.S. Court of Appeals for the Fourth Circuit rejected a Maryland regulation that set a minimum attachment point for stop-loss policies that employers purchased for their health care coverage.45 According to the court, Maryland tried to regulate employee health benefit

43 Jost & Hall, supra note 32, at 9; SUZANNE M. KIRCHHOFF & JANEMARIE MULVEY, CONG. RESEARCH SERV., R42735, MEDICAL LOSS RATIO REQUIREMENTS UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (ACA): ISSUES FOR CONGRESS 2 (2012) (describing 80% medical loss ratio for small group plans and 85% medical loss ratio for large groups).

44 Stop-loss policies can be written on a per-employee basis or on an aggregate basis. Thus, for example, the stop-loss policy might cover the costs above $20,000 for any one employee, or the policy might cover all costs that exceed an aggregate of $200,000 for the company. Buettgens & Blumberg, supra note 37, at 3; Jost & Hall, supra note 32, at 13-14. Large employers also purchase stop-loss policies.

plans (impermissible under ERISA) rather than insurance (permissible under ERISA) even though the regulations were “carefully drafted to focus directly on insurance companies issuing stop-loss insurance and not on the employee benefit plans themselves.” In the Fourth Circuit’s view, if states cannot regulate employee benefit plans directly, they also cannot do so indirectly. Under the Fourth Circuit’s reasoning, small employers can continue to exploit the self-insurance option and undermine the goals of ACA.

To be sure, some courts have noted that there must be limits to a principle that rejects indirect regulation of employee benefit plans. Otherwise, ERISA’s preemption of employee benefit plan regulation by states would swallow its exemption for regulation of state insurance law. The Maryland regulation suffered not only from its indirect effect on employee health plans but also from language that specifically targeted employee health plans rather than insurance policies in general. Hence, the legislature responded to the Fourth Circuit’s decision by reenacting a minimum attachment point for stop-loss policies without tying the regulation of stop-loss policies to their use in employee benefit plans. The new provision has not been challenged, and there is a good argument to be made that it solves the problems with the regulation that the Fourth Circuit struck down. Other states also have enacted regulations of stop-loss policies that appear to avoid the problems of the earlier Maryland provision. In this view, states can regulate the use of self-insurance by small employers as long as they reserve their regulation for the insurers that sell the stop-loss policies.

While careful drafting of stop-loss regulations seems to solve the self-insurance problem, there is still significant uncertainty. Some courts have signaled their approval, while others have not. With the different responses by courts, and

46 Id.
47 For example, the regulation’s coverage section had two parts, one of which described health insurance policies issued to employers, the other of which described stop-loss health insurance policies issued to employers. See 22 MD. REG. 913 (June 9, 1995).
48 MD. CODE ANN. INS. § 15-129 (West 2013).
49 HEALTH CARE LAW, supra note 4, at 1061; Jost & Hall, supra note 32, at 17-18; Korobkin, supra note 34, at 127-28. Actually, the new regulation was challenged by the same insurance company that challenged the original Maryland regulation, but the court dismissed the challenge as not being ripe, and the plaintiff withdrew from the Maryland insurance market instead of refileing the challenge at a later date. Korobkin, supra 34, at 128.
50 Compare, e.g., Wash. Physicians Serv. Ass’n v. Gregoire, 147 F.3d 1039, 1045 (9th Cir. 1998), with Hotz v. Blue Cross & Blue Shield of Mass., Inc., 292 F.3d 57, 59-60 (1st Cir. 2002).
the uncertainty about the application of ERISA preemption, many states may be reluctant to regulate stop-loss policies. A *Restatement of Health Care* could do much to reduce this reluctance if it took the view that regulations like the current Maryland statute are permissible under ERISA. As a result, access to affordable insurance under ACA would be better protected from compromise by small employers who take the self-insurance route.

III. HEALTH CARE EXCEPTIONALISM

Historically, legal doctrine has treated questions arising in health care differently than when they arise in other areas. For example, while corporations have been free to hire lawyers or other professionals, the corporate practice of medicine doctrine prevented businesses from employing physicians. And at one time, physicians and hospitals did not need to worry about liability under antitrust law for anticompetitive behavior. However, the law has eliminated much of the special treatment that it reserved for the health care sector. In the mid-1970s and early 1980s, the Supreme Court began to apply antitrust law to physicians and other health care providers. In addition, the corporate practice of medicine doctrine has been relaxed to some extent, and many hospitals employ physicians today. Just last year, the Supreme Court rejected an opportunity to view health care insurance as deserving exceptional treatment under the Commerce Clause when it considered the constitutionality of ACA's individual mandate to purchase health care coverage. Physicians and other health care providers may be special professionals and hold themselves to distinctive standards of ethics, but they also share many attributes with other people who are engaged in a profit-seeking business. The similarities between health care and other services often are more important than the differences.

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51 MARK A. HALL, IRA MARK ELLMAN & DAVID ORENTLICHER, HEALTH CARE LAW AND ETHICS IN A NUTSHELL 224 (3d ed. 2011) [hereinafter NUTSHELL].

52 HEALTH CARE LAW, supra note 4, at 1312 (also observing that health care antitrust exceptionalism reflected in part a broader principle of special treatment for the professions).


54 NUTSHELL, supra note 51, at 228.

55 Abigail R. Moncrieff, Understanding the Failure of Health-care Exceptionalism in the Supreme Court's Obamacare Decision, 142 CHEST 559 (Sept. 2012).
This section of the article considers the evolution of health care exceptionalism in public health law and health care antitrust law and discusses how a Restatement could encourage courts to better reflect the ways in which health care is both different from, and similar to, other sectors of the economy. Courts today do not give sufficient consideration to health care exceptionalism when applying the “commercial speech” doctrine to public health regulations. And with health care antitrust law, courts are too willing to invoke health care exceptionalism at times and not willing enough to do so at other times.

A. The First Amendment and the Public’s Health

In the past, courts allowed the government broad authority to regulate on behalf of the public health. For example, the U.S. Supreme Court upheld the constitutionality of a mandatory vaccination statute under a standard of rational basis review. According to the Court, the statute was permissible because it did not represent an “unusual, . . . unreasonable or arbitrary, requirement.” For a more recent illustration of a broad governmental authority to protect the public’s health, consider that Congress was allowed to prohibit all cigarette advertising on television or radio in a 1969 statute that took effect in 1971.

Over the past couple of decades, however, courts have looked more skeptically at public health regulations when hearing challenges to the regulations. For example, a three-judge panel on the U.S. Court of Appeals for the D.C. Circuit held that terminally ill patients should have greater access to experimental drugs than allowed by Food and Drug Administration (FDA) rules. And as a result of the Supreme

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56 Commercial speech refers to speech uttered by businesses to promote their products or services to potential customers. Advertising is the prototypical form of commercial speech. David Orentlicher, The Commercial Speech Doctrine in Health Regulation: The Clash Between the Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm, 37 AM. J.L. & MED. 299, 307 (2011).

57 Id. at 299.

58 197 U.S. 11 (1905).

59 Rational basis review is the most lenient standard for review under the Constitution. Statutes rarely fail to survive such review. ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 625-28, 678 (3d ed. 2006).

60 Jacobson, 197 U.S. at 27.


62 Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470, 486 (D.C. Cir. 2006), rev’d en banc, 495 F.3d 695 (D.C. Cir. 2007). To be sure, the D.C. Circuit sitting en banc reversed the panel’s decision 15
Court's invigoration of the commercial speech doctrine, the federal and state governments often have been stymied in their efforts to protect the public's health. The commercial speech doctrine substantially limits the authority of government to regulate the advertising or other promotional practices of the pharmaceutical and tobacco industries. Congress cannot prevent pharmacists from widely advertising their compounding services for prescription drugs, and state legislators cannot prevent drug company sales representatives from using data from patient prescriptions to target their promotional pitches to physicians. In addition, the FDA cannot impose the graphic warnings on cigarette packages that it unveiled in 2011.

While the government may have had too much freedom in the past to exercise its public health regulatory authority, it appears that courts have swung too far in the other direction. Recent decisions have made it too difficult for legislators and agencies to protect the public health. The examples of prescription data mining and cigarette warnings are illustrative.

1. Prescription Data Mining

For some time, health policy scholars have worried about the marketing activities of pharmaceutical companies. A number of studies have indicated that advertising and other promotional efforts unduly influence physician prescribing practices. Physicians may prescribe drugs or devices that are more expensive, less effective, or less safe than alternative options; they also may prescribe a drug or device when none is necessary. Months later, but the litigation led the FDA to relax its limitations on access to experimental drugs. George J. Annas, Cancer and the Constitution—Choice at Life's End, 357 New Eng. J. Med. 408, 411 (2007).


64 Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002). Congress was concerned about pharmacies using their authority under state law to create medications (through a process known as compounding) to evade rules requiring testing of experimental new drugs before they are marketed to the public. Normally, compounding is used for individual patients whose needs cannot be met by commercially available drugs. Id. at 360-62. Congressional concerns about problems with compounding were realized in 2012 when large-scale compounding resulted in many patients suffering serious infections of fungal meningitis. Kevin Outterson, Regulating Compounding Pharmacies After NECC, 367 New Eng. J. Med. 1969 (2012).


67 Jacobson's rational basis review was too deferential to legislative judgment.
needed. As a result, patients may suffer unnecessary harm to their health or their pocketbooks.

One marketing practice has raised particular concern because it entails the use of sensitive health information. Health information companies collect data about patient prescriptions from pharmacies and analyze the prescribing practices of individual physicians. The companies sell their analyses to pharmaceutical firms whose sales representatives can then better target their promotional pitches to doctors. If a salesperson is touting a drug to treat diabetes, for example, the salesperson would be interested in knowing which physicians frequently write prescriptions for diabetes drugs and whether physicians favor the company's drug or the drugs of other companies. The data analyses also can tell salespersons when a physician switches from the company's drug to another drug.

This "mining" of prescription data does not violate privacy laws because the patients' names are stripped from the collection of data. But the mining does compromise a key rationale for the confidentiality of patient information. Physicians promise that what their patients tell them will be protected from disclosure to others and will be used only for the benefit of the patients. This promise of confidentiality is critical to ensuring that people feel comfortable revealing information that is very sensitive. But when prescription data are used for marketing by pharmaceutical companies, patient information is used in ways that can harm patient welfare.

The U.S. Supreme Court rejected regulation of prescription data mining on the ground that the regulation targeted specific content (promotional practices) and particular speakers (drug companies). According to the Court, governmental regulation of

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69 Orentlicher, supra note 68, at 74-75.

70 Orentlicher, supra note 56, at 311.

speech must not favor some speakers over other speakers and some messages over other messages.\textsuperscript{72}

However, some degree of health care exceptionalism would have been useful. For example, the Court might have recognized that health care information is more private than other kinds of information and therefore deserving of greater protection.\textsuperscript{73} Or the Court might have followed the model of its decision in \textit{School Board of Nassau County v. Arline},\textsuperscript{74} in which it accorded deference to the views of public health officials.\textsuperscript{75} To be sure, \textit{Arline} involved statutory rather than constitutional interpretation. But the Court has sometimes allowed a degree of deference to professional expertise even when applying constitutional strict scrutiny,\textsuperscript{76} as when it deferred to the judgment of university officials on the value of diversity in higher education.\textsuperscript{77} A \textit{Restatement of Health Care Law} could encourage courts to exercise greater deference to public health officials when deciding whether regulations of pharmaceutical marketing satisfy constitutional requirements.

Greater deference to public health officials also would be helpful with warnings about the risks of smoking.

2. Cigarette Warnings

Tobacco use represents a major cause of preventable disease and death, and public health policies have done much to reduce the prevalence of cigarette smoking in the United States. As a result of high tobacco taxes and other measures, only 19\% of adult Americans smoked in 2011, compared to 40\% in 1965.\textsuperscript{78}

\textsuperscript{72} \textit{Id.} To be sure, the Court has upheld speaker-based restrictions in a number of situations. For example, the speech of government employees may be limited in ways that would not be tolerated for other persons. \textit{See, e.g., Connick v. Meyers}, 461 U.S. 138 (1983) (allowing dismissal of a local district attorney for questioning the internal policies of her office rather than speaking about matters of "public concern"); \textit{McCreary Cnty. v. ACLU of Ky.}, 545 U.S. 844 (2005) (rejecting the posting of the Ten Commandments by county executives on the walls of their courthouses).


\textsuperscript{74} 480 U.S. 273 (1987) (deciding whether the firing of a school teacher with tuberculosis amounted to discrimination on the basis of a disability).

\textsuperscript{75} \textit{Id.} at 288.

\textsuperscript{76} Strict scrutiny is the most exacting level of constitutional review.


Congress has especially worried about cigarette manufacturers misleading consumers about the health risks of smoking. Advertising is banned on radio and television, deceptive claims are prohibited, and cigarette packages must include warnings about the health consequences of smoking.

Because of concerns that the standard textual warnings on a pack of cigarettes often are not read or understood, Congress in 2009 mandated graphic color images to accompany new textual warnings. Graphic warnings have been required in other countries and have been more effective than textual warnings at ensuring that people understand the risks of smoking.

However, the U.S. Court of Appeals for the D.C. Circuit rejected the graphic images in August 2012. According to the court, the image mandate represented an unconstitutional infringement on the First Amendment rights of tobacco companies—the government was trying to make cigarette manufacturers spend their own dollars to promote the government’s antismoking message. Rather than seek Supreme Court review, the FDA decided to withdraw its images and develop revised versions.

There is room for more deference to public health officials on the questions whether graphic images are warranted and which ones should be used. Public health experts are in a much better position than courts to analyze the empirical evidence and assess the effectiveness of different options for ensuring that consumers are properly informed about the risks of smoking.

To be sure, courts should not accept at face value the representations of public health officials. We should not return to the rational basis review of Jacobson. But courts should give

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81 Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 518 (6th Cir. 2012).
82 Id. at 564-66. One of the images depicted a dead man lying on an autopsy table. R.J. Reynolds Tobacco Co, 696 F.3d at 1231 (2012) (Rogers, J., dissenting).
83 R.J. Reynolds Tobacco Co, 696 F.3d at 1221-22 (majority opinion). Earlier, the U.S. Court of Appeals for the Sixth Circuit upheld the authority of Congress to require graphic warnings. But that court did not review the actual warnings that were issued. Disc. Tobacco City & Lottery, 674 F.3d at 552-53.
85 And it’s not as if Congress rushed to use graphic warnings. Congress had tried to rely on the less intrusive requirement of textual warnings for many years before supplementing that requirement with its graphic images requirement. Disc. Tobacco City & Lottery, 674 F.3d at 526.
expert policy makers sufficient discretion to ensure that public health officials can take the steps necessary to safeguard the public's health.

A health care law Restatement could do much to guide the Supreme Court and lower courts as they further develop commercial speech principles. By recommending a meaningful degree of health care exceptionalism in First Amendment doctrine, a Restatement could help restore a better balance between First Amendment rights and public health needs.

While courts have cut back too much on their recognition of health care exceptionalism in public health, they have shown tendencies toward both underuse and overuse of health care exceptionalism in health care antitrust law. The judicial approach to hospital mergers is illustrative.

B. Antitrust Law and Hospital Mergers

Health care antitrust scholars have worried about the ways in which federal judges have responded when the government has challenged mergers of hospitals on antitrust grounds. In the view of antitrust experts, courts have been too willing to approve mergers, with the public suffering the anticompetitive effects of the consolidations. As the Affordable Care Act and other changes in health care encourage greater consolidation in the health care industry, it will become even more important for antitrust law to be applied correctly.

To some extent, past judicial decisions reflect a failure to give adequate weight to the ways in which health care markets differ from other kinds of markets. For example, courts may assume that patients are quite responsive to differences in price among hospitals and therefore are willing to travel significant distances for care. But the highly personal nature of patient-physician relationships and the preference for hospital care close to one's home can blunt patient sensitivity to the costs

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87 For example, ACA encourages the formation of "accountable care organizations" in which hospitals, doctors, and other health care providers join together to provide integrated health care to patients. Victor R. Fuchs & Leonard D. Schaeffer, If Accountable Canizations Are the Answer, Who Should Create Them?, 307 JAMA 2261, 2261-62 (2012); Ezekiel J. Emanuel, Why Accountable Care Organizations Are Not 1990s Managed Care Redux, 307 JAMA 2263, 2263-64 (2012).

88 Greaney, supra note 86, at 186-87.
of treatment. As a result, local consolidation can be enough to insulate hospitals from the competitive pressures that other businesses face from companies in neighboring communities.

Courts have especially failed to account for the fact that the widespread existence of health care insurance makes health care markets more susceptible to anti-competitive behavior than other markets. Normally, even businesses with substantial market power face constraints on their ability to raise prices. As prices rise, some consumers will be priced out of the market. Health care providers do not have to worry as much about pricing their customers out of the market because health insurance makes it possible for patients to afford even very expensive care.\(^8^9\)

Courts not only may incorrectly assume that health care decisions are made in the same way as other consumer decisions. Courts also may make the opposite mistake—they may wrongly conclude that participants in health care markets operate differently than their counterparts in other markets when they act in similar ways. As a result, judges may be too willing to excuse behavior by health care institutions that would elicit condemnation for organizations in other markets. For example, when not-for-profit hospitals have merged, some judges have overestimated the extent to which the hospitals' not-for-profit status would temper their anti-competitive behavior.\(^9^0\)

In short, when deciding whether hospital mergers are anti-competitive, courts may make two kinds of error. On one hand, judges may treat health care decisions similarly when they should be treated differently. On the other hand, judges may treat health care decisions differently when they should be treated similarly. When it comes to antitrust law, health care exceptionalism is underinclusive at some times and overinclusive at other times.

The authority of a Restatement on Health Care could do much to ensure that judicial decisions about hospital mergers and

\(^8^9\) I am grateful to Syd Arak for this point, which also is made in Clark C. Havighurst & Barak D. Richman, *The Provider Monopoly Problem in Health Care*, 89 OR. L. REV. 847, 863-64 (2011). One might expect insurers to police the pricing practices of health care providers, but societal objections to health care rationing limit the ability of insurers to do so. *Id.* at 863 n.46.

\(^9^0\) Greaney, *supra* note 86, at 187-88; Richman, *supra* note 86, at 131-33; Havighurst & Richman, *supra* note 89, at 855-56. Other courts have not assumed that mergers among not-for-profit hospitals are more benign than mergers among for-profit hospitals, *HEALTH CARE LAW, supra* note 4, at 1370. Analyses of hospital mergers by the Federal Trade Commission and the Massachusetts attorney general have discredited the view that not-for-profit hospitals will not exploit their market power. Havighurst & Richman, *supra* note 89, at 854-57.
other potentially anti-competitive behavior more accurately take account of the special nature of the market for health care.

A Restatement also could help courts sort through empirical evidence that often is not clear. Courts do not necessarily ignore empirical evidence in their health care antitrust decisions, but they may draw incorrect conclusions from data that can point in different directions. A Restatement could provide important guidance on key empirical questions for the courts.

CONCLUSION

Over the past few decades, as health care law has matured as a field of legal theory and practice, judges, legislators, and other government officials have become increasingly involved with major questions of legal policy for the health care sector. Often, these questions are quite complicated, and their resolution may suffer from the absence of an authoritative resource for policy makers. A Restatement of Health Care Law could do much to promote the development of appropriate legal rules in the future.

91 Richman, supra note 86, at 130-35.